

Attorney Docket Number: NASH-001/03US

Application No.: 10/601,314

Page 2

Listing of Claims:

1.-74. (Canceled)

75. (Currently amended) A method of reducing low density lipoprotein (LDL) while not significantly reducing high density lipoprotein (HDL) in a human subject, which method comprises administering over time a composition comprising an isolated mixture consisting essentially of theaflavin, theaflavin-3-gallate, theaflavin-3'-gallate, and theaflavin 3,3'-digallate in a therapeutically effective amount and for a time period sufficient to reduce the LDL while not significantly reducing the HDL over the time of administration.

76. (Previously presented) The method of claim 75, wherein the administration is continued for at least four weeks.

77. (Previously presented) The method of claim 75, wherein the administration is continued for at least twelve weeks.

78. (Previously presented) The method of claim 75, wherein the theaflavin, theaflavin-3-gallate, theaflavin-3'-gallate, and theaflavin 3,3'-digallate mixture is administered to the subject at a daily dosage rate of about 0.001mg/kg to about 200mg/kg body weight of the subject.

79. (Previously presented) The method of claim 78, wherein the theaflavin, theaflavin-3-gallate, theaflavin-3'-gallate, and theaflavin 3,3'-digallate mixture is administered at the daily dosage rate of about 0.1mg/kg to about 5mg/kg body weight of the subject.

80. (Previously presented) The method of claim 75, wherein the composition is an oral composition.

81. (Previously presented) The method of claim 80, wherein the oral composition is a tablet, capsule, powder, solution, suspension, emulsion, pill, pellet, sustained-release or formulation.

Attorney Docket Number: NASH-001/03US

Application No.: 10/601,314

Page 3

82. (Previously presented) The method of claim 80, wherein the oral composition contains the theaflavin, theaflavin-3-gallate, theaflavin-3'-gallate, and theaflavin 3,3'-digallate mixture in purified form in combination with a pharmaceutically acceptable vehicle.

83. (Previously presented) The method of claim 82, wherein the theaflavin, theaflavin-3-gallate, theaflavin-3'-gallate, and theaflavin 3,3'-digallate mixture is present at a level of about 5% to about 50% (w/w) of the composition administered.

84. (Previously presented) The method of claim 75, wherein the human subject suffers from hyperlipidemia.

85. (Currently amended) A daily dosage composition suitable for oral administration to a human subject over time, which dosage composition comprises an isolated mixture consisting essentially of theaflavin, theaflavin-3-gallate, theaflavin-3'-gallate, and theaflavin 3,3'-digallate in a therapeutically effective amount sufficient to reduce low density lipoprotein (LDL) while not significantly reducing high density lipoprotein (HDL), when the composition is delivered on a daily basis over time.

86. (Currently amended) The dosage composition of claim 85, wherein the dosage composition form is a tablet, capsule, powder, solution, suspension, emulsion, pill, pellet, sustained-release or formulation.

87. (Previously presented) The dosage composition of claim 85, wherein the theaflavin, theaflavin-3-gallate, theaflavin-3'-gallate, and theaflavin 3,3'-digallate of the composition is in purified form and is combined with a pharmaceutically acceptable vehicle.

88. (Previously presented) The dosage composition of claim 87, wherein the theaflavin, theaflavin-3-gallate, theaflavin-3'-gallate, and theaflavin 3,3'-digallate of the composition is present at a level of about 5% to about 50% (w/w) of the dosage form.

Attorney Docket Number: NASH-001/03US
Application No.: 10/601,314
Page 4

89. (Currently amended) The dosage composition of claim 85, wherein the isolated mixture is combined with an oil.

90. (Currently amended) The dosage composition of claim 89, wherein the isolated mixture is combined with vegetable oil.

91. (Currently amended) The dosage composition of claim 90, wherein the isolated mixture is combined with vegetable oil is encapsulated in a capsule.

92. (Previously presented) The dosage composition of claim 90, wherein the vegetable oil comprises corn oil, peanut oil, safflower oil, sunflower oil, soybean oil or a combination thereof.

93. (Previously presented) The dosage composition of claim 85, wherein the composition is to be administered for at least 4 weeks.

94. (Previously presented) The dosage composition of claim 85, wherein the composition is to be administered for at least 12 weeks.

95. (Previously presented) The dosage composition of claim 85, wherein the composition is for administration to a human subject that exhibits hyperlipidemia.

96. (Previously presented) The method of claim 75, wherein the theaflavin, theaflavin-3-gallate, theaflavin-3'-gallate, and theaflavin 3,3'-digallate mixture is administered to the subject at a daily dose of between about 70 mg to about 210 mg.

97. (Previously presented) The method of claim 81, wherein said capsule comprises a soft gel capsule or a capsule containing a liquid.

98. (Previously presented) The method of claim 82, wherein said pharmaceutically acceptable vehicle comprises a liquid vehicle, an excipient, an agent or a combination thereof.

Attorney Docket Number: NASH-001/03US

Application No.: 10/601,314

Page 5

99. (Previously presented) The method of claim 98, wherein said liquid vehicle comprises water, saline solution, aqueous dextrose, glycerol solutions or a combination thereof.

100. (Previously presented) The method of claim 98, wherein said excipient comprises starch, glucose, lactose, sucrose, gelatin, malt, rice, flour, chalk, silica gel, sodium stearate, glycerol monostearate, talc, sodium chloride, dried skim milk, glycerol, propylene, glycol, ethanol or a combination thereof.

101. (Previously presented) The method of claim 98, wherein said agent comprises a wetting agent, a stabilizing agent, an emulsifying agent, a pH buffering agent, a thickening agent, a lubricating agent, a coloring agent or a combination thereof.

102. (Previously presented) The method of claim 75, wherein the composition comprises between about 40% to about 50% theaflavin, between about 15% to about 25% theaflavin-3-gallate, between about 10% to about 14% theaflavin-3'-gallate, and between about 15% to about 25% theaflavin 3,3'-digallate mixture in purified form.

103. (Previously presented) The method of claim 82, wherein the oral composition comprises between about 40% to about 50% theaflavin, between about 15% to about 25% theaflavin-3-gallate, between about 10% to about 14% theaflavin-3'-gallate, and between about 15% to about 25% theaflavin 3,3'-digallate mixture in purified form.

104. (Previously presented) The dosage composition of claim 85, wherein the theaflavin, theaflavin-3-gallate, theaflavin-3'-gallate, and theaflavin 3,3'-digallate mixture is a daily dose of between about 70 mg to about 210 mg.

105. (Previously presented) The dosage composition of claim 86, wherein said capsule comprises a soft gel capsule or a capsule containing a liquid.

Attorney Docket Number: NASH-001/03US

Application No.: 10/601,314

Page 6

106. (Previously presented) The dosage composition of claim 87, wherein said pharmaceutically acceptable vehicle comprising a liquid vehicle, an excipient, an agent or a combination thereof.

107. (Previously presented) The dosage composition of claim 106, wherein said liquid vehicle comprises water, saline solution, aqueous dextrose, glycerol solutions or a combination thereof.

108. (Previously presented) The dosage composition of claim 106, wherein said excipient comprises starch, glucose, lactose, sucrose, gelatin, malt, rice, flour, chalk, silica gel, sodium stearate, glycerol monostearate, talc, sodium chloride, dried skim milk, glycerol, propylene, glycol, ethanol or a combination thereof.

109. (Previously presented) The dosage composition of claim 106, wherein said agent comprises a wetting agent, a stabilizing agent, an emulsifying agent, a pH buffering agent, a thickening agent, a lubricating agent, a coloring agent or a combination thereof.

110. (Previously presented) The dosage composition of claim 85, wherein the dosage composition comprises between about 40% to about 50% theaflavin, between about 15% to about 25% theaflavin-3-gallate, between about 10% to about 14% theaflavin-3'-gallate, and between about 15% to about 25% theaflavin 3,3'-digallate mixture in purified form.

111. (Previously presented) The dosage form of claim 106, wherein the dosage composition comprises between about 40% to about 50% theaflavin, between about 15% to about 25% theaflavin-3-gallate, between about 10% to about 14% theaflavin-3'-gallate, and between about 15% to about 25% theaflavin 3,3'-digallate mixture in purified form.

112. (Previously presented) A method of reducing low density lipoprotein (LDL) while not significantly reducing high density lipoprotein (HDL) in a human subject, which method comprises administering over time a composition consisting essentially of a mixture of theaflavin, theaflavin-3-gallate, theaflavin-3'-gallate, and theaflavin 3,3'-digallate in a

Attorney Docket Number: NASH-001/03US

Application No.: 10/601,314

Page 7

pharmaceutically effective amount and for a time period sufficient to reduce the LDL while not significantly reducing the HDL over the time of administration.

113. (Previously presented) The method of claim 112, wherein the theaflavin, theaflavin-3-gallate, theaflavin-3'-gallate, and theaflavin 3,3'-digallate mixture is administered to the subject at a daily dosage rate of about 0.001mg/kg to about 200mg/kg body weight of the subject.

114. (Previously presented) The method of claim 112, wherein the composition is an oral composition.

115. (Previously presented) The method of claim 114, wherein the oral composition is a tablet, capsule, powder, solution, suspension, emulsion, pill, pellet, sustained-release or formulation.

116. (Previously presented) The method of claim 112, wherein the theaflavin, theaflavin-3-gallate, theaflavin-3'-gallate, and theaflavin 3,3'-digallate mixture is present at a level of about 5% to about 50% (w/w) of the composition administered.

117. (Previously presented) The method of claim 112, wherein the composition comprises between about 40% to about 50% theaflavin, between about 15% to about 25% theaflavin-3-gallate, between about 10% to about 14% theaflavin-3'-gallate, and between about 15% to about 25% theaflavin 3,3'-digallate mixture in purified form.

118. (Previously presented) The method of claim 112, wherein the human subject suffers from hyperlipidemia.

119. (Previously presented) A method of reducing low density lipoprotein (LDL) while not significantly reducing high density lipoprotein (HDL) in a human subject, which method comprises administering over time a composition consisting essentially of a mixture of theaflavin, theaflavin-3-gallate, theaflavin-3'-gallate, and theaflavin 3,3'-digallate and at least one pharmaceutically acceptable vehicle and agent in a pharmaceutically effective amount and

Attorney Docket Number: NASH-001/03US
Application No.: 10/601,314
Page 8

for a time period sufficient to reduce the LDL while not significantly reducing the HDL over the time of administration.

120. (Previously presented) The method of claim 119, wherein the administration is continued for at least four weeks.

121. (Previously presented) The method of claim 119, wherein the administration is continued for at least twelve weeks.

122. (Previously presented) The method of claim 119, wherein the theaflavin, theaflavin-3-gallate, theaflavin-3'-gallate, and theaflavin 3,3'-digallate mixture is administered to the subject at a daily dosage rate of about 0.001mg/kg to about 200mg/kg body weight of the subject.

123. (Previously presented) The method of claim 122, wherein the theaflavin, theaflavin-3-gallate, theaflavin-3'-gallate, and theaflavin 3,3'-digallate mixture is administered at the daily dosage rate of about 0.1mg/kg to about 5mg/kg body weight of the subject.

124. (Previously presented) The method of claim 119, wherein the composition is an oral composition.

125. (Previously presented) The method of claim 124, wherein the oral composition is a tablet, capsule, powder, solution, suspension, emulsion, pill, pellet, sustained-release or formulation.

126. (Previously presented) The method of claim 125, wherein said capsule comprises a soft gel capsule or a capsule containing a liquid.

127. (Previously presented) The method of claim 119, wherein said pharmaceutically acceptable vehicle comprises a liquid vehicle, an excipient, an agent or a combination thereof.

128. (Previously presented) The method of claim 127 wherein said liquid vehicle comprises water, saline solution, aqueous dextrose, glycerol solutions or a combination thereof.

Attorney Docket Number: NASH-001/03US

Application No.: 10/601,314

Page 9

129. (Previously presented) The method of claim 127 wherein said excipient comprises starch, glucose, lactose, sucrose, gelatin, malt, rice, flour, chalk, silica gel, sodium stearate, glycerol monostearate, talc, sodium chloride, dried skim milk, glycerol, propylene, glycol, ethanol or a combination thereof.

130. (Previously presented) The method of claim 127 wherein said agent comprises a wetting agent, a stabilizing agent, an emulsifying agent, a pH buffering agent, a thickening agent, a lubricating agent, a coloring agent or a combination thereof.

131. (Previously presented) The method of claim 119, wherein the theaflavin, theaflavin-3-gallate, theaflavin-3'-gallate, and theaflavin 3,3'-digallate mixture is present at a level of about 5% to about 50% (w/w) of the composition administered.

132. (Previously presented) The method of claim 119, wherein the composition comprises between about 40% to about 50% theaflavin, between about 15% to about 25% theaflavin-3-gallate, between about 10% to about 14% theaflavin-3'-gallate, and between about 15% to about 25% theaflavin 3,3'-digallate mixture in purified form.

133. (Previously presented) The method of claim 119, wherein the human subject suffers from hyperlipidemia.

134. (Currently amended) A method, comprising:

administering to a human a composition comprising a shell and a an isolated mixture consisting essentially of theaflavin, theaflavin-3-gallate, theaflavin-3'-gallate, and theaflavin 3,3'-digallate formulated to reduce the LDL while not significantly reducing the HDL in the human.

135. (Previously presented) The method of claim 134, wherein the shell defines an interior and the mixture is disposed within the interior of the shell.

Attorney Docket Number: NASH-001/03US
Application No.: 10/601,314
Page 10

136. (Currently amended) The method of claim 134, wherein the ~~mixture is an isolated~~ mixture of theaflavin, theaflavin-3-gallate, theaflavin-3'-gallate, and theaflavin 3,3'-digallate is in purified form and is combined with a pharmaceutically acceptable vehicle.

137. (Previously presented) The method of claim 136, wherein the mixture comprises between about 40% to about 50% theaflavin, between about 15% to about 25% theaflavin-3-gallate, between about 10% to about 14% theaflavin-3'-gallate, and between about 15% to about 25% theaflavin 3,3'-digallate mixture in purified form.

138. (Currently amended) A method, comprising:

administering to a human a composition comprising a an isolated mixture consisting essentially of theaflavin, theaflavin-3-gallate, theaflavin-3'-gallate, and theaflavin 3,3'-digallate formulated to reduce the LDL while not significantly reducing the HDL in the human, a weight of the mixture of theaflavin, theaflavin-3-gallate, theaflavin-3'-gallate, and theaflavin 3,3'-digallate being at least 5% of a weight of the composition.

139. (Previously presented) The method of claim 138, wherein the weight of the theaflavin, theaflavin-3-gallate, theaflavin-3'-gallate, and theaflavin 3,3'-digallate is at least 15% of the weight of the composition.

140. (Previously presented) The method of claim 138, wherein the weight of the theaflavin, theaflavin-3-gallate, theaflavin-3'-gallate, and theaflavin 3,3'-digallate is between 5% and 50% of the weight of the composition.

141. (Previously presented) A daily dosage composition suitable for oral administration to a human subject over time, which dosage composition consists essentially of a mixture of theaflavin, theaflavin-3-gallate, theaflavin-3'-gallate, and theaflavin 3,3'-digallate in an amount sufficient to reduce low density lipoprotein (LDL) while not significantly reducing high density lipoprotein (HDL), when the composition is delivered on a daily basis over time.

Attorney Docket Number: NASH-001/03US

Application No.: 10/601,314

Page 11

142. (Previously presented) A daily dosage composition suitable for oral administration to a human subject over time, which dosage composition consists essentially of a mixture of theaflavin, theaflavin-3-gallate, theaflavin-3'-gallate, and theaflavin 3,3'-digallate and at least one pharmaceutically acceptable vehicle and agent in a therapeutically effective amount sufficient to reduce low density lipoprotein (LDL) while not significantly reducing high density lipoprotein (HDL), when the composition is delivered on a daily basis over time.

143. (Currently amended) A composition, ~~comprising~~ consisting essentially of:

a mixture of theaflavin, theaflavin-3-gallate, theaflavin-3'-gallate, and theaflavin 3,3'-digallate, the mixture being formulated to reduce low density lipoprotein (LDL) while not significantly reducing high density lipoprotein (HDL) in a human, a weight of the mixture being at least 5% of a weight of the composition.

144. (Previously presented) The composition of claim 143, wherein the weight of the mixture is at least 15% of the weight of the composition.

145. (Previously presented) The composition of claim 143, wherein the weight of the mixture is between 5% and 50% of the weight of the composition.

146. (Previously presented) The composition of claim 143, wherein the mixture is an isolated mixture of theaflavin, theaflavin-3-gallate, theaflavin-3'-gallate, and theaflavin 3,3'-digallate.

147. (Previously presented) The composition of claim 143, further comprising:
a shell, the mixture being disposed within the shell.